

Applicants: HOWARD L. WEINER *et al.*
Serial No.: 08/279,275
Filed: July 22, 1994

25. (Unchanged) The method of claim 20 wherein said autoantigen is contained in tissue that is the site of attack in the autoimmune disease.

(1982)
26. (Unchanged) The method of claim 22 wherein said autoantigen is contained in tissue that is the site of attack in the autoimmune disease.

REMARKS

Reconsideration of this application is respectfully requested.

37 C.F.R. §1.129 (2d)

This Amendment is made under 37 C.F.R. §1.129(a). Payment of the fee of \$760.00 is enclosed. The Commissioner is hereby authorized to charge deposit account no. 04-0100 any deficiency in this amount, and to credit any excess to this same account.

PENDING CLAIMS

Following entry of this Amendment, claims 1, 9, 11-13, 15-18, and 20-26 will be pending.

OBJECTION AND REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 1, 2, 9, 10-13, 15-18, and 20 stand rejected, and the specification objected to, under 35 U.S.C. §112, first paragraph. The current rejection is on the basis that the present claims encompass autoimmune diseases beyond those for which specific clinical results have been submitted. The Examiner states that there are numerous autoimmune diseases having different etiologies and symptoms and questions whether the results submitted thus far with respect to specific diseases, such as multiple sclerosis and rheumatoid arthritis, support the present claims.

Applicants have included herewith such evidence, showing that a common mechanism of action is shared in the oral or enteral administration of autoantigens to treat T-cell mediated autoimmune disease according to the present invention. The mechanism involves induction of tolerance to the fed antigen, i.e. elicitation of regulatory T-cells. This treatment does not involve the etiology of each disease: it is only directed to a symptom, namely the abnormal immune response directed against the afflicted organ or tissue. The treatment dampens this abnormal response by acting on the immune system directly. The treatment is thus independent of the tissue or organ involved. The immune system of afflicted animals has been shown to respond to this treatment (e.g. NOD diabetes; collagen-induced arthritis; EAE) in very disparate settings. Therefore, the immune system is capable of responding, and the generality of this approach has been demonstrated. Notably, applicants have treated these experimental autoimmune disease models after the animals had been sensitized, i.e., after the autoimmune-like response was initiated. For this reason also, the generality of the approach has been demonstrated. It is

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respectfully submitted that in view of this common mechanism, and applicants' pioneering work in this field, the present claims, as amended, have been shown to be enabled.

INFORMATION DISCLOSURE STATEMENT

In reviewing the present file, applicants note that the Form 1449 submitted with the Information Disclosure Statement of October 24, 1996 has not been returned to applicants. Applicants request that the Examiner return the initialed copy of the form 1449 (i.e., and consider any references that have not been considered).

CONCLUSION

This application is respectfully submitted to now be in condition for allowance. Issuance of a notice to that effect is respectfully requested.

Respectfully submitted,

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